

Amendment
U.S. Patent Application No. 09/536,351

REMARKS

Reconsideration and continued examination of the above-identified application are respectfully requested.

The amendment to the claims further define what the applicants regard as their invention. Full support for the amendment can be found throughout the present application, including the claims, for instance, claims 2 and 17-19, and page 9 of the present application. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

At page 2 of the Office Action, the Examiner indicates that the finality of the previous rejection is removed. Furthermore, the Examiner has decided to enter the amendment that was set forth in the Amendment After Final filed May 3, 2002.

At page 2 of the Office Action, the Examiner rejects claims 14 and 17-19 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner now argues that the term "storage stable" is indefinite and is open to wide interpretation. The Examiner asserts that the present application refers to a 14 day period, and sets no limit on acceptable % degradation to constitute a stable preparation.

The Examiner also argues that the term "substantially free of organics" is also not clear. The Examiner asserts that Kleeberg (U.S. Patent No. 5,695,763), states that surfactants are solvents and therefore the Examiner asserts that surfactants are solvents and vegetable oil can dissolve some things.

Furthermore, at page 3 of the Office Action, the Examiner relies on Howard J. Milks, which refers to the use of vegetable oil as well as other oils. For the following reasons, this rejection is respectfully traversed.

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Clearly, the present application provides numerous examples of what is meant by storage stable and one skilled in the art in the pesticide area would clearly understand what is meant by storage stability. To assist the Examiner, the applicants have amended claim 14 of the present application to recite, wherein the formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remained after one year of storage at 25°C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container.

Further, Kleeberg is substantially different from the claimed invention in several ways. First, Kleeberg does not teach or suggest the use of a vegetable oil, as in the claimed invention. Furthermore, Kleeberg suggests using organic solvents such as ketones, alcohols (such as 1-butanol, pentanol), esters (such as acetic ethyl ester, acetic acid n-butyl ester) or halogenated hydrocarbons (such as dichloromethane, trichloromethane). Second, the material in Kleeberg is a powdery concentrate. Additionally, unlike the claimed invention, the actual storage life of the material is not specified. As for the materials stored in the surfactant, it can only be stored for several months. Therefore, Kleeberg does not teach or suggest a "storage stable" pesticide formulation, as that term is used in the claimed invention. Furthermore, Kleeberg does not teach or suggest a storage stable formulation that comprises at least one vegetable oil and at least one non-ionic surfactant.

With respect to Howard J. Milks reference, this reference is not related to the claimed invention, and the Examiner has not indicated the relevance of Howard J. Milks reference. Howard J. Milks reference only relates to use of vegetable oil as well as other oils in vitamins, not azadirachtin formulations. This cited reference is irrelevant to the technology. Accordingly, one

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skilled in the art would not look to Howard J. Milks reference to overcome the deficiencies of Kleeberg.

With respect to the term "substantially free of solvents," according to MPEP §2173.05(b)(D), the term "substantially" when used in conjunction with another term to describe a particular characteristic of the claimed invention (e.g., substantially free of organic solvents) is considered definite. Furthermore, the Examiner's assertion is incorrect that the applicants, in their Amendment of November 20, 2001, stated that no organics were added. The applicants in their November 20, 2001 stated that no organic solvent is intentionally added. Accordingly, the formulation of the claimed invention is substantially free of organic solvents. Additionally, the meaning of the term "organic solvent," is clear to one having ordinary skill in the art, especially in light of the portions of the specification quoted. An organic solvent does not include vegetable oil. To one of ordinary skill in the art, an organic solvent could be ethanol, xylene, and other organic solvents. Thus, the term "organic solvent" is a term widely recognized by those skilled in the art. For instance, Hawley's Condensed Chemical Dictionary (14th Ed.) (2001) clearly recognizes the term "organic solvent" and shows groups that include esters, ethers, ketones, amines, nitrated and chlorinated hydrocarbons, and the like. Clearly, this is quite different from a vegetable oil. In fact, the same Hawley's Condensed Chemical Dictionary defines vegetable oil in a manner that clearly would not be an organic solvent. Thus, the Examiner's position with respect to the term "organic solvents" is not supported by the record, and clear evidence has been submitted by the appellants to show that the Examiner's position is not accurate. Furthermore, support for recitation of substantially free of organic solvents in claims 17-19 exists on page 4, lines 19-26, and page 7, lines 31-33 of the present application. Accordingly, the rejection under 35 U.S.C. §112, second paragraph, should be withdrawn.

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At page 3 of the Office Action, the Examiner rejects claims 1 and 14 under 35 U.S.C. §102(b) as being anticipated by Butler et al. (U.S. Patent No. 5,352,697). The Examiner argues that Butler et al. shows the use of azadirachtin with epoxidized vegetable oils and surfactant to provide a storage stable formulation with no water present. For the following reasons, this rejection is respectfully traversed.

As recited in claims 1 and 14 of the present application, the claimed invention is a pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin or a neem seed extract, wherein the formulation contains less than 2% by weight water, based on the weight of the formulation. Furthermore, claims 1 and 14 further recite that the pesticide formulation is substantially free of organic solvents. Additionally, claim 14 recites that the formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after one year in storage at 25°C in a sealed container, or such that at least at about 25% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container. The Butler et al. formulation and the claimed invention differ, at least, in that Butler et al. does not teach a formulation that contains less than 2% by weight water, based on the weight of the formulation. The lack of water is an important feature of the claimed invention, since the presence of water degrades azadirachtin, as is set forth at page 5, lines 19-23 of the present application. Additionally, neem seed usually contains 30-40% moisture during harvest and dried neem seed usually contains 10-15% water. Accordingly, although Butler et al. does not specifically mention the presence or absence of water, it seems inherent that the formulation of Butler, et al. includes more than 2% by weight water, based on the weight of the formulation. Furthermore, most of the examples in Butler et al. use the traditional organic solvents instead of vegetable oils. For example, in example 1 of Butler et al., ethanol, ethyl acetate, acetonitrile, isopropanol, methanol, and the like

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are used. Likewise, examples 2-10 in Butler et al. show azadirachtin containing neem seed extract in an aromatic petroleum distillate, which is an organic solvent. The advantages of not using organic solvents are illustrated at page 7, lines 31-33 of the present application. Therefore, Butler et al. does not teach the claimed invention. Accordingly, the rejection under 35 U.S.C. §102(b) over Butler et al. should be withdrawn.

At the bottom of page 3 of the Office Action, the Examiner then rejects claims 1 and 14 under 35 U.S.C. §102(b) as being anticipated by Carter et al. (U.S. Patent No. 5,124,349). The Examiner asserts that Carter et al. shows a formulation containing azadirachtin, neem oil, vegetable oil, and 1-10% surfactant. The Examiner acknowledges that no water is specified in Carter et al. The Examiner further asserts that column 3, lines 35-54 of Carter et al. states that preferably less than 1% by weight water is present. For the following reasons, this rejection is respectfully traversed.

Carter et al. does not teach the invention set forth in claims 1 and 14, because each of the claims recites the presence of a vegetable oil. Carter et al. simply does not teach the presence of vegetable oil. The Examiner refers specifically to the top of column 4 for support of the presence of a vegetable oil, but at column 4 Carter et al. only shows para-amino benzoic acid and esters thereof. These substances are clearly not vegetable oils and therefore the Examiner's argument that Carter et al. shows vegetable oil is neither understood nor supported by a reading of Carter et al. Accordingly, the rejection under 35 U.S.C. §102(b) over Carter et al. should be withdrawn.

At page 4 of the Office Action, the Examiner rejects claims 1 and 14-16 under 35 U.S.C. §103(a) as being unpatentable over Dimetry et al. and Carter et al. The Examiner asserts that it would be obvious to one skilled in the art to combine the teachings of Dimetry et al. with Carter et al. The Examiner asserts that Dimetry et al. shows the presence of azadirachtin with a non-ionic

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emulsifier and sesame oil. The Examiner relies on Carter et al. in the manner as set forth above. The Examiner attempts to argue that it would be obvious to one of ordinary skill in the art to utilize Dimetry's sesame oil in Carter. For the following reasons, this rejection is respectfully traversed.

As recited in claim 1, the claimed invention relates to a pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin, wherein the formulation contains less than about 2% by weight water, based on the weight of the formulation, wherein the formulation is substantially free of organic solvents. The formulation of Dimetry et al. and the claimed invention differ in that Dimetry et al. only shows a formulation with water, as can be seen from column 1 at page 396. However, the claimed invention contains less than about 2% by weight water, based on the weight of the formulation. The lack of water is an important feature of the claimed invention, because the presence of water degrades azadirachtin, as is set forth at page 5, lines 19-23 of the present application and as set forth in the Declaration of Dr. M. C. Gopinathan dated April 30, 2002.

Additionally, Dimetry et al. does not teach or suggest the use of a formulation having storage stable azadirachtin, which is recited in the claims. The formulation of Dimetry et al. is not storage stable because its formulation contains water, and azadirachtin is unstable in the presence of water and other solvents. To further illustrate, one of the applicants conducted comparative experiments to compare the claimed invention with Dimetry et al. As shown in the Declaration of Dr. M.C. Gopinathan submitted under 37 C.F.R. §1.132 on April 30, 2002, the formulation of Dimetry et al., which contained water along with small amounts of sesame oil and a surfactant, had a very low storage stability. In other words, the storage stability of the formulation of Dimetry et al. was poor compared to the product of the claimed invention that contained substantially no water.

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Thus, the formulation of Dimetry et al. is not a storage stable product and is different, for the reasons stated above, from the claimed invention.

Furthermore, Dimetry et al. does not teach or suggest a storage stable formulation that contains less than 2% by weight water, based on the weight of the formulation, and comprises at least one non-ionic surfactant, as found in claim 14 of the present application, wherein the formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after one year of storage at 25° C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container, and wherein said formulation is substantially free of organic solvents.

In addition to not teaching or suggesting a storage stable formulation that contains less than 2% by weight water, based on the weight of the formulation, wherein the formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after one year of storage at 25° C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container. Dimetry et al. does not teach or suggest including at least one non-ionic surfactant and sesame seed oil, as recited in claim 15 of the present application. Dimetry et al. also does not teach or suggest including sorbitan polyoxyethylene, as recited in claim 16.

The Examiner acknowledges that Dimetry et al. does not teach or suggest the claimed invention. Therefore, Examiner further argues that the deficiencies of Dimetry are resolved by Carter et al. which shows a low amount of water and further shows storage stability. However, only through the improper use of hindsight would one combine Carter et al. with Dimetry et al. Dimetry et al. shows a usable formulation in and of itself and Carter et al. does the same. As stated above, evidence has been provided previously to show the differences between Dimetry et al. and the

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claimed invention. Accordingly, one skilled in the art would have no motivation to alter these formulations. Also, Carter et al. uses solvents and does not disclose the use of vegetable oil. Therefore, no motivation exists to alter the formulation of Carter et al. with Dimetry et al. Accordingly, the rejection of claims 1 and 14-16 under 35 U.S.C. §103(a) over Dimetry et al. and Carter et al. should be withdrawn.

Finally, at page 5 of Office Action, the Examiner rejects claims 2-12, 23, and 24 under 35 U.S.C. §112, first paragraph. The Examiner asserts that the application is enabling only for showing a 28 day storage but does not provide enablement for storage stability for one year at 90%. For the following reasons, this rejection is respectfully traversed.

Clear enablement for this storage stability is present in the application. The Examiner has shown no technical reasons to doubt the statements present in the application. Further, the 28 day accelerated test is considered predictive of the 1 year stability of a product. To assist the Examiner, the applicants have amended claims 2 and 3 to further recite that the storage stability is alternatively based on an accelerated aged 28 day test. Accordingly, the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

CONCLUSION


In view of the foregoing remarks, the applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37

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C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to
said Deposit Account.

Respectfully submitted,


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Thrice Amended) A pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin, wherein said formulation contains less than about 2% by weight water, based on the weight of the formulation, and wherein said formulation is substantially free of organic solvents.

2. (Twice Amended) A pesticide formulation comprising at least one vegetable oil, at least one non-ionic surfactant, and azadirachtin, wherein said formulation is storage stable and wherein said formulation contains less than about 2% by weight water, based on the weight of the formulation, wherein said formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after 1 year of storage at 25°C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container.

3. (Thrice Amended) A storage stable pesticide formulation comprising at least one vegetable oil, at least one non-ionic surfactant, and a neem seed extract, wherein said neem seed extract comprises azadirachtin, and wherein said formulation contains less than about 1/2% by weight water, based on the weight of the formulation, wherein said formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after 1 year of storage at 25°C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container.

14. (Thrice Amended) A storage stable pesticide formulation formed by mixing at least one vegetable oil, at least one non-ionic surfactant, and at least one neem extract together to form said formulation, wherein said neem extract comprises at least azadirachtin, and wherein said formulation contains less than about 2% by weight water, based on the weight of the formulation,

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wherein said formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after 1 year of storage at 25°C in a sealed container, or such that at least at about 25 wt% of the azadirachtin A originally present remains after an accelerated aged test of 28 days at 54° C in a sealed container, and which said formulation is substantially free of organic solvents.